

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL**

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER:

03 -- 0 01

2. STATE:

MAINE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL  
SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE(S)

1/1/03

5. TYPE OF PLAN MATERIAL (CHECK ONE):

☐ NEW STATE PLAN

☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN

☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

7. FEDERAL BUDGET IMPACT:

a. FFY 03 \$ 6.7 million

b. FFY 04 \$8.9 million

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:  
ATT. 4.19-B P.3A; ATTACHMENT TO ATTACHMENT 3.1A P. 5

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (If Applicable): ATT. 4.19-B P.3A;  
ATTACHMENT TO ATTACHMENT 3.1A P. 5

SUBJECT OF AMENDMENT: REVISE DESCRIPTION OF MEDICAID PHARMACY SUPPLEMENTAL REBATES AND THEIR  
RELATIONSHIP TO MEDICAID PHARMACY PRIOR AUTHORIZATIONS. THE DESCRIPTION OF SUPPLEMENTAL REBATES IS  
MOVED FROM 4.19-B TO 3.1A. 185,000 INDIVIDUALS ARE POTENTIALLY AFFECTED

11. GOVERNOR'S REVIEW (Check One):

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT

☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☒ OTHER, AS SPECIFIED

COMMISSIONER, DEPT. OF HUMAN SERVICES

12. SIGNATURE OF STATE AGENCY OFFICIAL:

*Peter E. Walsh*

13. TYPED NAME:

PETER WALSH

14. TITLE:

Acting Commissioner, Maine Department of Human  
Services

15. DATE SUBMITTED: FEBRUARY 24, 2003

16. RETURN TO:

*Maine 03-0011*  
*Approved: 06/27/03*  
*Effective: 01/01/03*

EUGENE GESSOW

Director, Bureau of Medical Services  
#11 State House Station

442 CIVIC CENTER DRIVE  
Augusta, ME 04333-0011

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

Attachment to  
Attachment 3.1-A, Page 5

State/Territory: Maine

**AMOUNT, DURATION, AND SCOPE OF MEDICAL  
AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY  
NEEDY**

Item

**12a Prescribed Drugs**

Limited to prescribed medications, but including certain prescribed over-the-counter drugs. Utilization of certain covered drug products may be restricted by means of the prior authorization process, in compliance with federal law. Drugs that do not require prior authorization are considered preferred.

The State is in compliance with Section 1927 of the Act. Based on the requirements of Section 1927 of the Act, the State has the following policies for the supplemental rebate program for the Medicaid population:

- a. A June 16, 2003 version of the rebate agreement entitled "Supplemental Rebate Agreement" between the State and a drug manufacturer for drugs provided to the Medicaid population has been authorized by CMS.
- b. Funds received from supplemental rebate agreements will be reported to CMS. The State will remit the Federal portion of any supplemental rebates collected.
- c. Manufacturers with supplemental rebate agreements are allowed to audit utilization data.
- d. The unit rebate amount is confidential and cannot be disclosed in accordance with section 1927(b)(3)(D) of the Social Security Act (the Act). No changes will be made to the agreement without CMS authorization. Supplemental rebates received pursuant to these agreements are only for the Medicaid Program.
- e. The State may negotiate the Supplemental Rebate Agreement that would classify any covered drug as preferred for as long as the agreement is in effect.
- f. The prior authorization process for covered outpatient drugs conforms to section 1927(d)(5) of the Act.

**Item 12b Dentures**

Limited to permanent dentures, with prior authorization required for partial dentures. Individuals age 21 and over with qualifying medical conditions, submitting requests for prior authorization, will be considered for full and partial dentures or other appropriate dental services under the adult dental services criteria. Prior to approving adult dental services the department determines that the provision of those services is medically necessary to correct or ameliorate an underlying medical condition, and will be cost-effective in comparison to the provision of other covered medical services for the treatment of that condition.

**Item 12d Eyeglasses**

Limited to first pair of eyeglasses for individuals not covered under EPSDT when the power is equal to or greater than +10 diopters. The volume purchase of eyeglasses limits the selection of frames and lenses to a basic assortment from one supplier.

TN No. 03-001

Supersedes

TN No. 01-009

Approval Date: 6-27-03 Effective Date: 1/01/03

**-+SUPPLEMENTAL REBATE AGREEMENT**  
**June 16, 2003 Version**

This Supplemental Rebate Agreement ("Agreement") is dated as of this \_\_\_\_\_ day of \_\_\_\_\_, 200\_, by and between the State of Maine Department of Human Services ("State") and \_\_\_\_\_ ("Pharmaceutical Manufacturer").

**RECITALS**

**WHEREAS**, the State has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates for the benefit of the State's Medicaid members providing such agreements are authorized by the Centers for Medicare & Medicaid Services (CMS); and

**WHEREAS**, \_\_\_\_\_ is willing to provide supplemental rebates to the State based on the actual dispensing of \_\_\_\_\_ Covered Products under the State's Medicaid program.

**NOW THEREFORE**, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties, intending to be legally bound, agree as follows:

1. **Definitions.** As used herein, the following terms shall have the meanings set forth below:
  - 1.1 **"Agreement"** means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.
  - 1.2 **Pricing definitions applicable to State Supplemental Rebate Formulas in Attachment B:**
    - 1.2.1 **"Average Wholesale Price" ("AWP")** shall mean the lowest published price of the Covered Product by National Drug Code ("NDC") as published by First DataBank or Redbook on the first day of the calendar quarter that corresponds to the calendar quarter for which the State utilization data for the Covered Product is reported to \_\_\_\_\_.
    - 1.2.2 **"Average Manufacturer Price" ("AMP")** shall mean the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. This definition shall be consistent with the definition set forth in section 1927(k)(1) of the Social Security Act.
    - 1.2.3 **"Wholesale Acquisition Cost" ("WAC")** shall mean the price paid by retail stores when purchasing drugs distributed by wholesalers.
    - 1.2.4 **"Guaranteed Net Price"** shall mean the final fixed price of the drug assured by the Manufacturer to the State. It shall be calculated as AWP minus the CMS rebate minus the State Supplemental Rebate necessary to equal the guaranteed net price to the State by \_\_\_\_\_ for the Covered Product for the calendar quarter.
  - 1.3 **"Basic Rebate"** shall mean, with respect to the Covered Product, the quarterly payment by \_\_\_\_\_ pursuant to \_\_\_\_\_'s Medicaid Drug Rebate Agreement made in

accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

- 1.4 **"CMS"** shall mean the Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.
- 1.5 **"Competitive Product"** shall mean \_\_\_\_\_ that competes with Covered Product. \_\_\_\_\_ are defined as \_\_\_\_\_, and any other branded \_\_\_\_\_ approved by the FDA during the term of this Agreement.")
- 1.6 **"Covered Product"** shall mean \_\_\_\_\_ and as a covered outpatient drug in 1927 (k)(i) of the Social Security Act for which the state made payment under the state plan.
- 1.7 **"CPI Rebate"** means, with respect to the Covered Product, the quarterly payment by \_\_\_\_\_ pursuant to \_\_\_\_\_'s Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).
- 1.8 **"Maximum Allowable Cost (MAC)"** shall mean the lowest reimbursement rate established by the State for \_\_\_\_\_.
- 1.9 **"Medicaid Drug Rebate Agreement"** shall mean the agreement in place between \_\_\_\_\_ and the U.S. Secretary of Health and Human Services, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). CMS is the agency within HHS having the delegated authority to operate the Medicaid Program.
- 1.10 **"Medicaid Member"** shall mean any person enrolled in the State Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.
- 1.11 **"Pharmacy"** shall mean a facility licensed to dispense legend drugs, and enrolled as a State Medicaid provider.
- 1.12 **"Preferred Drug List"** shall mean a document listing various pharmaceutical products covered by the State Medicaid Program for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products. All drugs of manufacturers with OBRA 90 rebate agreements with CMS will remain covered, although some drugs that are Non-Preferred will require Prior Authorization consistent with Section 1927 of the Social Security Act. The DUR Committee will review drugs on a monthly or bi-monthly basis to make recommendations to the Department for drugs to be listed as Preferred or Non-Preferred on the PDL.
- 1.13 **"State Medicaid Program"** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Members.
- 1.14 **"State Supplemental Rebate"** shall mean an amount paid on a calendar quarter basis by \_\_\_\_\_ to State for covered product utilization under State's fee for service Medicaid

program pursuant to this Agreement. The State Supplemental Rebate is in Attachment B. For the purpose of this agreement the designated formula shall be formula \_\_\_\_\_.

- 1.15 “**Step Care**” shall mean a potentially defined order of therapeutic choices within either the preferred or non-preferred drug list categories. (See Section 2.1c)
- 1.16 “**Unit**” means a single capsule of Covered Product.
- 1.17 “**USC**” means the United States Code. All references in this agreement to USC chapters or sections shall include any successor, amended, or replacement statute.

## 2.0 State Obligations

### 2.1 **Preferred Drug List.** To be eligible for the Supplemental Rebates specified in Attachment B:

- a) State shall place and maintain Covered Product on the Preferred Drug List, it being agreed that utilization shall be eligible for the State Supplemental Rebate only in quarters in which Covered Product is listed on the Preferred Drug List; and
- b) State shall place Covered Products in an advantaged position relative to non-preferred Competitive Products regarding Preferred Drug List status, and
- c) Depending on the designated preferred tier, the State shall place Covered products in an advantaged position relative to other preferred products (Step Care). Non-Preferred and Step Care drugs may be subject to prior authorization. Criteria for approving prior authorization will be the responsibility of the DUR Committee. These criteria will meet generally accepted clinical standards of practice for the proper use of drugs, and
- d) State shall have on file the fully executed CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.

### 2.2 **Preferred Drug List Documentation and Publication.** State shall communicate the inclusion of Covered Product on the Preferred Drug List to State Medicaid Program providers through the standard notification process

### 2.3 **Invoicing.** State shall invoice \_\_\_\_\_ for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS. State shall submit the State Supplemental Rebate invoice to \_\_\_\_\_ within sixty (60) days after the end of each calendar quarter in which the Covered Product subject to such State Supplemental Rebate was paid for by State. Any amended invoice shall be submitted by State within fifteen (15) months after the end of the calendar quarter in which Covered Product was paid for by State.

### 2.4 **Patient Information.** State, its agents, employees and contractors shall not provide to \_\_\_\_\_ any patient identifiable information or protected health information (“PHI”) or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

- 2.5 **Approval of Generic.** If during the duration of this Agreement a generic equivalent of any Competitive Product should become available, State will allow Covered Product to remain on the Preferred Drug List so long as the net cost to the State, as defined in Attachment B, is not more than the lowest reimbursement cost for a generic equivalent.

### 3.0 \_\_\_\_\_ Obligations

- 3.1 **State Supplemental Rebate Payment.** \_\_\_\_\_ agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid by the State and dispensed to Medicaid Members by Pharmacies for each calendar quarter that Covered Products are included in the Preferred Drug List. \_\_\_\_\_ shall pay to State the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. Nothing in this Agreement shall be construed to relieve \_\_\_\_\_ from its obligation to pay Medicaid Drug Rebates for utilization by State Medicaid Members. State shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under its approved state plan.
- 3.2 **Payment Timeframe.** \_\_\_\_\_ shall pay to State the State Supplemental Rebate amount to which State is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days after receipt of State's invoice.
- 3.3 **Incomplete Submission.** \_\_\_\_\_ shall have no obligation to pay State Supplemental Rebate amounts for claims that are not submitted as part of an invoice in accordance with Section 1.16 of this Agreement. \_\_\_\_\_ shall notify State or its designee of any incomplete submission within thirty-eight (38) days of \_\_\_\_\_'s receipt of such submission pursuant to Section 1.16.
- 3.4 **Over/Underpayment.** If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally accepted applicable procedures followed by State or CMS in disputes concerning Medicaid Drug Rebates. Any overpayment shall be deducted from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, State will refund any such overpayment to \_\_\_\_\_ within thirty (30) days of the parties' acknowledgement of the overpayment. \_\_\_\_\_ will remit any underpayment to State within thirty (30) days of the parties' acknowledgement of such underpayment.
- 3.5 **Discretion to Market.** Nothing in this Agreement shall be construed to prohibit \_\_\_\_\_ from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that \_\_\_\_\_ is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail Pharmacies and dispensed to Medicaid Members. If \_\_\_\_\_ elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, \_\_\_\_\_ shall make every reasonable effort to notify State prior to such actions.

### 4.0 Term and Termination

- 4.1 **Effective Date.** This Agreement shall be effective \_\_\_\_\_, and shall continue in force through \_\_\_\_\_ 2004, unless it is terminated sooner pursuant to the following:
- a) **Breach.** If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following delivery. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.
  - b) **Without Cause.** Either party may terminate this Agreement without cause as of the end of any calendar quarter by giving the other party ninety (90) days prior written notice.
- 4.2 **Accrued Obligations/Remedies.** The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.
- 4.3 **Execution, Amendment and Waiver.** This Agreement shall be binding only upon signature by both parties. This Agreement, or any provision, may be altered, amended, or waived by written amendment executed by both parties as authorized by CMS.
- 5.0 **Miscellaneous**
- 5.1 **Record Keeping and Audit.** During the term of this Agreement and for a period of three (3) years thereafter, both parties to the Agreement shall use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At \_\_\_\_\_'s written request, State shall make such information available for inspection by \_\_\_\_\_ representatives or its designated auditors during regular business hours. Upon written request, each party shall otherwise have the right to inspect, up to once each year, all such relevant books and records of the other party to verify compliance with the terms of this Agreement.
- 5.2 **Indemnification.** \_\_\_\_\_ shall be responsible for and shall indemnify and hold State harmless from all claims resulting from the acts or omissions of \_\_\_\_\_ and any Subcontractor. State shall be responsible and shall indemnify and hold \_\_\_\_\_ harmless from all claims resulting from the acts or omissions of State.
- 5.3 **Confidentiality.** Except as otherwise may be required to be disclosed by law and in accordance with the Rebate Agreement between the U.S. Secretary of Health and Human Services and the drug manufacturers, information disclosed by \_\_\_\_\_ in connection with this Agreement will not be disclosed by the State. Each party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of three (3) years thereafter.

- 5.4 **Notices.** Any notice required or permitted to be given by either party to the other shall be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**State:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- 5.5 **Force Majeure.** Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.
- 5.6 **Assignment.** Neither party shall have the right to assign this Agreement to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any obligations that have accrued prior to such assignment.
- 5.7 **No Waiver of Rights.** The failure of either party to insist upon the strict observation or performance of any provision of this Agreement or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate.
- 5.8 **Entire Agreement.** This Agreement contains the entire agreement and understanding of the parties. This Agreement (including Attachments) may not be amended or modified except upon the written agreement of both parties.
- 5.9 **Governing Law.** This Agreement shall be governed by the laws of the State of Maine. In the event of a lawsuit involving this Agreement, venue shall be proper only in Kennebec County, Maine.
- 5.10 **Effect of Future Laws.** In the event of the enactment, promulgation, rescission, modification or interpretation of any law or regulation after the date hereof which would (a) materially adversely affect the manner in which either party is obligated to perform under this Agreement, (b) adversely affect for either party the net prices or State Supplemental Rebates or other terms applicable under this Agreement, or (c) have the effect of requiring the net prices or State Supplemental Rebates or other terms applicable under this Agreement to be extended or offered to any third party, each party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement affected by such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party. If the parties do not agree within



sixty (60) days of a party's written request for negotiations, either party may terminate this Agreement with respect to the affected Covered Products upon expiration of the sixty (60) day period, with immediate effect.

- 5.11 **Compliance with Law.** In connection with its respective obligations under this Agreement, each party shall comply with all applicable federal, state and local laws and regulations, including without limitation any disclosure or consent requirements.
- 5.12 **Authority.** State and \_\_\_\_\_ each represent and warrant to the other that the person signing below has all requisite legal power and authority to execute this Agreement on behalf of each party and each party shall thereby be bound.
- 5.13 **Best Price Contingency.** The effectiveness of this Agreement shall be contingent on \_\_\_\_\_'s Best Price and AMP not being affected by State Supplemental Rebates.
- 5.14 **CMS Approval Contingency.** The effectiveness of this Agreement shall be contingent on receipt of CMS approval by State, as evidenced by the CMS Exemption Letter, attached hereto as Exhibit C and incorporated by reference.

IN WITNESS WHEREOF, this Agreement has been executed by the parties set forth below:

\_\_\_\_\_

State of Maine Department  
of Human Services

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

## **ATTACHMENT A**

### **Covered Products**

The products to which this Supplemental Rebate Agreement shall apply are the following:

<b>NDC</b>	<b>Brand</b>	<b>Strength</b>	<b>Package Description</b>

## **ATTACHMENT B**

### **Rebate Formula**

**ATTACHMENT C**  
**CMS Exemption Letter**